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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,172	12/21/2001	Yoichi Takahama	322732000401	2837

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,172	TAKAHAMA ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/13/06& 08/28/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-43,51,55-57,59 and 61-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-43,51,55-57,59 and 61-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *8/28/&[illegible]06* 8/30
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on July 13, 2006, and the supplement amendment filed on August 28, 2006, wherein the later one is to replace the previous amendment filed on July 13, 2006. Claims 31, 36, 60 have been amended. Claims 1-30, 44-50, 52-54, 58, 60 have been canceled. New claims 64-68 are added. Claims 31-43, 51, 55-57, 59, 61-68 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Interview Summery

A telephonic interview had been conducted on August 28 & August 30, 2006 with Applicants representative, Attorney Gregorey P. Applicants had been noticed and acknowledged the inadvertent mistake made in the amendment filed on July 13, 2006. Applicants elected to submit the supplemental amendment to correct the mistake in order to expedite the prosecution.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Terminal Disclaimer

The Terminal Disclaimer filed on July 13, 2006 has been acknowledged and it effectively overcome the obvious type double patenting rejection over the US patent 6,379,886B1.

New matter

The amendments filed on 07/13/2006 and August 28, 2006 are objected to under 35 U.S.C. 132 because they introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials, which are not supported by the original disclosure, are (1). In claims 31, lines 7-8, "wherein the first HCV antigen comprising a first synthetic peptide having a molecular weight of less then

10,000" ; and (2) in claim 36, line 8 "the second HCV antigen comprising a second synthetic peptide "

The specification has been carefully reviewed, while the specification teaches some of the conjugated HCV antigen are made as synthetic peptides according to the HCV sequences disclosed in the Official Published patent Gazette No. 50821993, the specification does not define "a synthetic peptide" is referred to a HCV synthetic peptide antigen. Therefore, a broadest reasonable interpretation of the amendment "a synthetic peptide" in claims 31 and 36 can be any synthetic peptide not exclusively to a HCV synthetic peptide. In particular, applicants have deleted the limitation of HCV antigen that defines the cited synthetic peptide in claim 36. More particularly, applicants have used this new amendment to argue against the prior art rejection in the response. Applicants assert that : the cited reference does not teach the conjugated HCV antigen comprising a synthetic peptide conjugated with a carrier protein ... (See response filed on August 28, 2006, lines 8-9 of page 10). The question is therefore, raised that the amendment of claims 31 and 36 has changed the scope of the claims read on a conjugated HCV antigen comprising any or all synthetic peptide. However, said broad scope of the claims are not supported by the specification as it was originally filed, and it constitutes a new matter issue.

Applicant is required to cancel the new matter in the reply to this Office Action.

New Matter Rejection

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 31-43, 51, 56-57, 59, 61-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains new subject matters, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As described above, the specification has been carefully reviewed, while the specification teaches some of the conjugated HCV antigen are made as synthetic peptides according to the HCV sequences disclosed in the Official Published patent Gazette No. 50821993, the specification does not define "a synthetic peptide" is referred to a HCV synthetic peptide antigen. Therefore, a broadest reasonable interpretation of the amendment "a synthetic peptide" in claims 31 and 36 can be any synthetic peptide not exclusively to a HCV synthetic peptide. In particular, applicants have deleted the limitation of HCV antigen that defines the cited synthetic peptide in claim 36. More particularly, applicants have used this new amendment to argue against the prior art rejection in the response. Applicants assert that : the cited reference does not teach the conjugated HCV antigen comprising a synthetic peptide conjugated with a carrier protein ... (See response filed on August 28, 2006, lines 8-9 of page 10). The question is therefore, raised that the amendment of claims 31 and 36 has changed the scope of the claims read on a conjugated HCV antigen comprising any or all synthetic peptide. However, said broad scope of the claims is not supported by the specification as it was originally filed, and it constitutes a new matter issue. Applicants are not in the possession for having the claimed diagnostic agent comprising a conjugated HCV antigen, wherein the conjugated antigen comprises either one or more of any type of a synthetic peptide other than the synthetic HCV peptide antigen(s).

3. Applicant can overcome the rejection by canceling the new matter in the reply to this Office Action.

4. **It is noted on the record since one embodiment of the scope of claims 31 and 36 still read on the conjugated HCV antigen is made the synthetic HCV peptide antigen, the following office action regarding the rejections made by the previous office actions are based on that embodiment of the scope.**

Double Patenting

5. In response to the previous office action, Applicants do not address or argue about the rejection, they elect to hold this issue in abeyance until such time claims are held allowable.

6. Applicants have amended claims and added new claims in the response. Upon considering the pending clams, claims 36, 37, 38, 41, 42, 43, 51, 55-59, 61-68, 31, 31, 32, 33, 34, 64 and 65-68 of the current Application are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 14, 18, 19, 20, 22, 23, 24, 25, 26, 27 of copending application 11/126,662, because the conflict claims are still read as an obvious version each from other, and they are not patentably distinct from each other.

7. Claim 36 and its dependent claims 37, 38, 41, 42, 43, 61, 63, 65 of the current application are directed to a diagnostic agent comprising a solid phase sensitized with (a) genetic recombinant HCV antigen having a molecular weight of 10,000 or more and (b) one or more conjugated HCV antigen, wherein the conjugated HCV antigen comprising a synthetic HCV peptide antigen conjugated with a carrier protein, preferably selected from the group consisting of HCV non-structural region protein, core or HCV structural region protein NS4 and NS5 having molecule weight less than 10,000, wherein the genetic recombinant HCV is selected from a HCV nonstructural protein NS3 that can also be conjugated with a carrier protein. The carrier protein is a water soluble protein selected from BSA, ovalbumin or hemocynin. The solid phase comprise carrier particles.

8. The conflict claims 13, 14, 18, 19, 20, 22, 23, 24 of the copending application are also directed to a diagnostic agent comprising a solid phase sensitized with (a) genetic recombinant HCV antigen having a molecular weight of 10,000 or more and (b) one conjugated HCV antigen, wherein the conjugated HCV antigen comprising a synthetic peptide conjugated with a carrier protein and the synthetic peptide, preferably selected from HCV structural protein, core with less than 10,000 in weight, wherein the genetic recombinant HCV is the nonstructural protein, NS3 that can also be conjugated with a carrier protein. The carrier protein is a water soluble protein selected from BSA, ovalbumin or hemocynin. The solid phase comprise carrier particles.

9. To this context, the conflict claims of the copending application are drawn to one of the species of the generically claimed diagnostic agent of claims 36 and its dependent claims, they have overlapping scope. The species of the claimed diagnostic reagent in claims 13, 14, 18, 19, 20, 22, 23, 24 , 27 of the copending application contains the limitations of the generic claims

claim 36 and its dependent claims of the current application. These claims anticipate the 36 37, 38, 41, 42, 43, 61, 63, 65 of the current application.

10. Claims 25 and 16 of the copending application and claims 66-68 of the copending application are also considered as an obvious type of diagnostic agents. Although the claims 66-68 only specify the 1st conjugated HCV antigen as core antigen, the 2nd conjugated antigen as HCV NS4, whereas claims 25-26 and 16 of the copending application also specify the 1st conjugated synthetic HCV antigen as core and the 2nd conjugated synthetic HCV antigen as NS4, wherein the genetic recombinant HCV antigen is HCV NS3. But none of them specify which HCV synthetic antigen as the 3rd conjugated antigen.

11. Claims 25-26 of the copending application and claims 31-35, 51, 55, 59, 62, 64 of the current application are also not patentable distinct each from other each because they are also presented as an obvious version of a diagnostic reagent. All of them are directed to a HCV antigen conjugated with a carrier protein with same molecular weight (claim 64/claim 27). The claims 31 and its dependent claims are presented as an obvious version overt the claims 25 and 26 in the copending application 11,126,662.

12. An obvious-type double patenting rejection is appropriate where the conflict claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (fed. Cir. 1985).

13. To this context, the previous obvious double patenting is still maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BAOQUN LI, PHD
PATENT

Bao Qun Li